NHG RESEARCH EDUCATION

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Issue 30, April 2018

[Update 2] Is My Study Human Biomedical Research?

Background

The Human Biomedical Research Act was passed in 2015 to set out the regulatory frameworks for Human Biomedical Research (HBR), and Human Tissue for use in research. The objectives of the HBR framework are to regulate human biomedical research, to protect the safety and welfare of human research subjects and to regulate the conduct of certain types of human biomedical research that are considered more 'sensitive'.

The purpose of this article is to help researchers understand what constitutes as HBR studies in 3 steps.

Tips and Recommendations

Step 1: Determine if your study is HBR.

Does this study involve

- ❑ a) Human gametes or human embryos; **or**
- ❑ b) Cytoplasmic hybrid embryos; **or**
- ☐ c) The introduction of any human-animal combination embryo into an animal or human; **or**
- ☐ d) The introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of the development (including a prenatal animal foetus or animal embryo)
- ☐ e) Any entity created as a result of any process referred to in (c) or (d) above

If YES → This is HBR.

Please use the Restricted HBR Checklist to determine if the study is a restricted human biomedical research.

If NO → Proceed to Step 2.

Step 2: Identify if your study objective falls within the scope of HBR.

Does the intent of my study involve:

- ☐ The prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; **or**
- ☐ The restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; **or**
- ☐ The performance or endurance of human individuals.

If NO → This is Non-HBR.

If YES → Proceed to Step 3.

Step 3: Identify if the methodology employed also falls under the scope of HBR.

Does my study methodology involve:

- ☐ Subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual; **or**
- ☐ The use of any individually-identifiable biological material obtained from the human body; **or**
- ☐ The use of any individually-identifiable health information.

If YES → This is HBR.

**Note: Your study falls under HBR only if you have answered 'Yes' in both steps 2 and 3.*

If NO → This study is not HBR as it does not deploy the methodology as listed under step 3.

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PIs who intend to conduct restricted HBR study as per the definition of the HBRA Fourth Schedule would need to additionally obtain approval from MOH before starting the research.
This checklist will assist you in determining if your study falls under Restricted Human Biomedical Research:

Determining if your study falls under Restricted Human Biomedical Research

Does this study involve any of the below:		
☐ a) human eggs or human embryos; **or** ☐ b) cytoplasmic hybrid embryos; **or** ☐ c) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells); **or** ☐ d) human-animal combination embryos created in-vitro by using human gametes and animal gametes; **or** ☐ e) human-animal combination embryos created in-vitro by using one human pronucleus and one animal pronucleus; **or** ☐ f) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo; **or** ☐ g) the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction; **or** ☐ h) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; **or** ☐ i) any entity created as a result of any process referred to in (f), (g) and (h) above	**If YES to any** **If NO to all**	Restricted HBR Not Restricted HBR

Submission Process / Instructions

Please inform your respective Institution Clinical Research Unit/Office of your intention to conduct restricted HBR prior to submitting the DSRB/IRB application.
If you're a NHG PI, please contact the NHG Research Institution (RI) Secretariat at NHGRISecretariat@nhg.com.sg if you need any clarification.
For non-NHG Principal Investigators, please contact your respective institution's Clinical Research Unit/Office for assistance to obtain your CorpPass.

For more information about the Human Biomedical Research Act, please refer to the Ministry of Health website via the link below:

https://www.moh.gov.sg/content/moh_web/home/legislation/legislation_and_guidelines/human-biomedical-research-act.html

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